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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/808,078 | 03/24/2004 | Mark Tsonton | END-5293 | 7086 |
| 27777 | 7590 | 01/24/2006 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | ROY, ANURADHA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/808,078 | Applicant(s) TSONTON ET AL. | |
| | Examiner Anuradha Roy | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/24/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/24/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 17, 18, & 20 are objected to because of the following informalities: Claim 17 & 18 state dependence on Claim 19. Additionally, Claim 20 states dependence on Claim 20. Examiner believes this was an inadvertent error and Applicant intended for Claims 17 & 18 to be dependent on Claim 16, and Claim 20 to be dependent on Claim 19; therefore, the claims have been examined in this manner. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 & 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al. (US Publication No. 2003/0028094).

Regarding claim 1, Kumar et al. discloses a biopsy device suitable for use with a magnetic resonance imaging machine, said device comprising an elongated needle (1810) for receiving tissue therethrough, the needle comprising: a distal needle segment (1811) comprising a tissue receiving port (1812), the distal needle segment formed of a first material [0045] that does not interfere with MRI imaging of a portion of the distal needle segment associated with the tissue receiving port; a proximal needle segment

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(1890 & 1820) disposed proximally of the tissue receiving port, the proximal needle segment formed at least in part of a second material different from said first material [0188].

With regard to claims 6-8, Kumar et al. discloses a proximal needle segment, wherein the second material comprises a metal and is non-magnetic [0186] and is selected from the group comprising aluminum, aluminum alloys, stainless steel, titanium, titanium alloys, and combinations thereof [0186]. Examiner contends wire is a form of metal according to the definition found in the Webster dictionary online.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 & 9-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. in view of Huitema et al. (US Patent No. 6,626,849).

Regarding claims 2, 3, 16 –18, & 19, Kumar discloses a biopsy device suitable for use with a magnetic resonance imaging machine and comprising: a distal needle segment (1811) comprising a tissue receiving port (1812) communicating with a cutter lumen, the distal needle segment formed of a first material [0045]; a proximal needle segment (1890 & 1820) formed at least in part of a metal [0188], the proximal needle segment providing at least a portion of the cutter lumen (Figure 18 & 19), and wherein

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said metal is spaced proximally at least about 0.5 inch from a proximal edge of said tissue receiving port [0079]. Kumar, however, does not teach of the first material being a non-metallic material. However, Huitema et al. teaches of a non-metallic and nonmagnetic material (Column 4, lines 25-31) for the distal region of the needle. It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Huitema et al. to utilize a non-metallic and non-magnetic material on the needle with Kumar et al. in order to prevent an obscured image of the lesion by the needle.

"The image of the lesion will show the metal probe, and this is problematic because the image of the probe can obscure the image of the lesion. Therefore, there has been a desire to have a generally non-metallic biopsy probe of the type described above." (Column 2, lines 59-63)

Regarding claim 4, Huitema et al. further discloses a distal needle segment, wherein the first material comprises a liquid crystal polymer (Column 4, lines 25-31).

With regard to claims 9-11, Huitema et al. discloses a device further comprising a distal piercing tip (Figure 1 & 60) disposed distal of the tissue receiving port, wherein the distal piercing tip comprises a non-metallic material and is selected from the group comprising ceramics and glasses (Column 7, lines 30-34).

In regards to claim 12, Huitema et al. discloses a device, wherein the proximal needle segment (33) and the distal needle segment provide a continuous, smooth cutter lumen (32).

In regards to claim 13, Huitema et al. discloses a device, wherein the proximal needle segment and the distal needle segment provide a continuous vacuum lumen (34).

In regards to claim 14, Huitema et al. discloses a device, wherein the needle comprises at least passage (36) extending from the vacuum lumen to an outer surface of the needle.

In regards to claim 15, Huitema et al. discloses a device, wherein the distal needle segment comprises a plurality of passages (Figure 4 & 23) extending from the vacuum lumen to the outer surface of the needle.

With regard to claim 20, Huitema et al. discloses a device, wherein the distal needle segment comprises at least a portion of a vacuum lumen (Figure 4 & 34).

Additional Claim Rejections - 35 USC § 103

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. in view of Sapatova et al. (US Publication No. 2003/0203140).

Kumar et al. discloses the aforementioned element of a biopsy device. Kumar et al., however, does not directly disclose a melt flow index of at least about 15 grams/minute. However, Sapatova et al. teaches of a melt flow index of at least about 15 grams/minute ([0015] & [0047]). It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Sapatova et al. to have a melt flow index of at least 15 grams/minute with Kumar et al. in order to allow for the "implementation of multi-cavitation tools, and a commensurate increase in productivity" [0047].

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rhad et al. (US Publication No. 2003/0109801) discloses a MRI compatible surgical device and Karasawa (US Patent No. 5,738,632) discloses material in used for MRI apparatus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~



MAX F. HINDENBURG
SENIOR PATENT EXAMINER
EBC CENTER 3700